

## REMARKS

The Office Action has been carefully considered and the foregoing amendment made in response thereto. The present status is as follows:

- Claims 1-8, 10, and 12-26 are pending in the application.
- Claims 1-8, 10, and 12-26 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description.
- Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Floyd (U.S. Pat. No. 4,904,450).
- Claims 1-8, 10, 12-23, 25, and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore (U.S. Pat. No. 5,855,289) in view of Babson (U.S. Pat. No. 4,639,242).
- Claim 24 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore (U.S. Pat. No. 5,855,289) in view of of Babson (U.S. Pat. No. 4,639,242), in further view of Neeley et al. (U.S. Pat. No. 5,164,575).

In view of the above amendment and following remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-8, 10, and 12-26.

1. Applicants thank the Examiner for participating in a telephone interview with Applicants' undersigned representative held on October 3, 2001. Applicants respectfully submit that this Amendment and Response is consistent with the discussion therein.

2. Claims 1-8, 10, and 12-26 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description. Applicants respectfully traverse this rejection.

The Office Action states that the term "planar" (added to claim 1 in Applicants' last response dated 15-Jun-01) is not disclosed in the specification. Office Action p. 2. The Office Action further states that there is no mention of an outwardly extending planar or flat portion of the anti-rotation lug 18. *Id.*

Applicants' respectfully submit that use of the term "planar" is clear to one of skill in the art. The terms of a claim carry their ordinary meaning, unless it appears that the inventor used them differently. *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1579 (Fed. Cir. 1988). The adjective "planar" is defined as flat. *The American Heritage® Dictionary of the*

*English Language, Fourth Edition*, Houghton Mifflin Company, 2000. The term “planar,” as used throughout the instant application, conveys a meaning that is not inconsistent with the dictionary definition.

With respect to disclosure of the outwardly extending planar or flat portion of the anti-rotation lug 18, Applicants’ respectfully submit that a drawing may, by itself, constitute a written description of the invention if it reasonably conveys to one of ordinary skill that the inventor possessed the invention. [U]nder proper circumstances, drawings alone may provide a “written description” of an invention as required by §112. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ 2d 1111, 1118 (Fed. Cir. 1991). Adequate description under the first paragraph of 35 U.S.C. §112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an [Applicant] had possession of the concept of what is claimed. *Ex parte Parks*, 30 USPQ 2d 1234, 1236–37 (B.P.A.I. 1993).

As noted in their 15-Jun-01 response, the planar surface of Applicants’ anti-rotation lug 18 is clearly visible in Applicants’ FIGS. 1, 2, 4, and 5. Reference to FIGS. 1 and 2 shows that each anti-rotation lug 18 includes flat sides that are perpendicular to the outer surface of the body 12. In other words, the sides are planar surfaces that extend radially with respect to the longitudinal axis of the body 12. Further, as depicted in FIG. 5, each anti-rotation lug 18 has a longitudinal extent (i.e., the planar sides extend along the direction of the longitudinal axis of the body 12).

Applicants respectfully submit that the planar surface portion of the anti-rotation lug 18 was adequately disclosed in the drawings as filed. Consequently, Applicants respectfully submit that the application reasonably conveys the subject matter of claim 1. Furthermore, claims 2-8, 10, and 12-26, all rejected under 35 U.S.C. § 112, first paragraph, depend, directly or indirectly, from independent claim 1. In view of the above, Applicants respectfully submit that the application reasonably conveys the subject matter of these claims as well.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-8, 10, and 12-26 under 35 U.S.C. § 112, first paragraph.

3. Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Floyd (U.S. Pat. No. 4,904,450). Applicants respectfully traverse this rejection.

As shown in Floyd FIGS. 2 and 3 (perspective views), Floyd discloses lugs 13 that are semi-cylindrical projections from casement 11. It is evident from these figures that the outer surface of each of Floyd's lugs 13 is curved and not planar (i.e., not "flat," as the term is used throughout the instant application, as discussed above). Furthermore, Floyd only mentions the lugs in passing at col. 4, l. 16, which identifies the lugs 13, but offers no further details regarding their shape or structure. Consequently, it is clear that Floyd neither teaches nor discloses lugs 13 that have any shape other than semi-cylindrical, as depicted in FIGS. 2 and 3.

The planar nature of each anti-rotation lug 18 disclosed and claimed by Applicants is a relevant aspect of Applicants' invention. As discussed in the specification at p. 13, ll. 3-12, during operation of the automated test apparatus, the body 12 is placed in the bore 52. Within the bore 52 are ramps 56, each having a substantially vertical ramp face 58 that, as shown in FIG. 7A, is also substantially flat. The abutting planar surface of each anti-rotation lug 18 reacts against a respective ramp face 58 to prevent rotation of the body 12 when the cap 14 is turned. For effective reaction against each ramp face 58, each anti-rotation lug 18 is configured to have a planar surface that makes good contact with the former. If each anti-rotation lug 18 had a non-planar surface, contact with each ramp face 58 would not be optimized, due to the substantially flat configuration of the latter. The reduced contact area reduces the area through which the anti-rotation forces pass between each ramp face 58 and abutting anti-rotation lug 18. This means that, when placed in the bore 52, the body 12 would not be reliably prevented from rotating as the cap 14 is turned. To illustrate, if the anti-rotation lugs 18 had the semi-cylindrical shape as taught by Floyd, only a line contact between each anti-rotation lug 18 and the ramp face 58 would result. During operation of the automated test apparatus, the rotational force applied to the cap 14 by the rotatable interface 42 could cause the anti-rotation lugs 18 to "jump" or bypass the ramp faces 58, causing the body 12 to rotate in the bore 52. Rotation of the body 12 when in the bore 52 defeats an automation benefit of Applicants' invention.

In view of the above, Applicants respectfully submit that the presence of the term “planar” (i.e., a structural limitation) in claim 1 clearly and patentably distinguishes Applicants’ invention over Floyd.

Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Floyd.

4. Claims 1-8, 10, 12-23, 25, and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore (U.S. Pat. No. 5,855,289) in view of Babson (U.S. Pat. No. 4,639,242). Applicants respectfully traverse this rejection as applied to the claims as amended.

Moore teaches the use of ribs 64, 70 on a lid 34 that are adapted to flex under a centrifugal load and expand the peripheral member 38 of the lid 34. Col. 5, ll. 34-36. This expansion increases the sealing force applied by the lid 34, tightening the seal between the gasket 54 and the cylindrical wall 26. Col. 6, ll. 43-47. The downward deflection of the ribs 64, 70 also focuses the compressive force applied by the lid 34 away from the center of the stopper 84 onto the area of the stopper 84 that coincides with the annular ring 68. Col. 7, ll. 18-20. This enhances the fluid-tight and air-tight seal between the stopper 84 and the receptacle 22. Col. 6, ll. 29-35. The mating surfaces of the stopper 84 and the receptacle 22 are smooth, thereby ensuring an effective seal. Moore FIG. 7. Thus, the ribs 64, 70 purportedly serve to increase the effectiveness of the two seals when the container 10 is in use. Because the amount of deflection and corresponding expansion increase in proportion to the centrifugal force, the seals are improved as the force increases. As stated in the Office Action, “Moore does not teach the use of at least one anti-rotation lug about the body outer surface.”

Babson discloses outwardly extending vanes 31 disposed about the periphery of a vessel 1. Col. 3, ll. 38-48. The bottom edge of each vane 31 is beveled, resulting in an oblique return of the vane 31 in to the outer wall of the vessel 1. Babson FIG. 3. The topmost inner surface of the vessel 1 may fluted by including V-grooves 32. Col. 3, ll. 66-67; FIG. 3. It is this fluted version of the vessel 1 that may be sealed with a tight-fitting cap 41. Col. 3, ll. 49-53; FIG. 4. According to Babson, the purpose of the vanes 31 is to interact with a fluid (e.g., a high-speed jet of air) and cause the vessel 1 to spin about its longitudinal axis. *Id.* The spinning creates a centrifugal force that promotes the mixing or separation of the contents of the vessel 1,

depending on configuration of the vessel 1 and the rotational speed. Col. 2, ll. 39-45; col. 2, l. 60 – col. 3, l. 7.

Applicants' invention is nonobvious, because the Babson vanes 31 address a problem that is different from that addressed by Applicants' anti-rotation lugs 18. An invention is nonobvious if the elements cited in the prior art typically deal with different problems. *See, e.g., Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984). The Babson vanes 31 are concerned with the problem of promoting rotation, while Applicants' anti-rotation lugs 18 are concerned with the problem of preventing rotation. In light of these mutually exclusive objectives, a person of ordinary skill, on reading Babson, would be discouraged from following the path set out in Babson, or would be led in a direction divergent from the path that Applicants took. *See, e.g., In re Gurley*, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994).

The combination of Moore with Babson is insufficient to make Applicants' invention obvious to one of ordinary skill in the art. There must be some reasonable expectation of success for the suggested combination. *See, e.g., In re Dow Chem. Co.*, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). Combining Moore with Babson would result in a nonfunctional structure, because the sealable version of Babson includes V-grooves 32 that would interfere with the proper sealing action between the smooth mating surfaces as disclosed by the Moore cap structure. The irregular surface formed by the Babson V-grooves 32 would be unable to mate securely with the surface of the Moore stopper 84, thereby compromising the seal integrity. Consequently, a combination of Moore with Babson would be inoperative, as well as destroy the intended function of each reference.

Notwithstanding the above, Applicants have amended claim 1 to include the further structural limitation that the longitudinally disposed surface of the anti-rotation lug 18 has "a lowermost edge that is substantially perpendicular to said body outer surface." No new matter has been added, because the structure of the lowermost edge of the anti-rotation lug 18 is disclosed in FIG. 5. Examination of FIG. 5 clearly shows that the lowermost edge is substantially perpendicular to the outer surface of the body 12. Applicants respectfully submit that FIG. 5 conveys to one having ordinary skill in the art, in accordance with *Vas-Cath* and *Ex parte Parks*, the claimed limitation.

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As with the geometry with the planar side of the anti-rotation lug 18, the geometry of the lowermost edge of the anti-rotation lug 18 is a relevant aspect of Applicants' invention. As discussed in the specification at p. 13, l. 13 – p. 14, l. 4, when the capped vial 10 is inserted in the vial sleeve 64, each anti-rotation lug 18 is received by an axially extending slot 66. Similarly, when the body 12 is installed in the bore 52, each anti-rotation lug 18 contacts the ramps 56. If the lowermost edge of the anti-rotation lug 18 is not substantially perpendicular to the outer surface of the body 12 (in other words, not substantially perpendicular to the longitudinal axis of the body 12), each anti-rotation lug 18 would present a reduced surface area for contact with the bottom of each axially extending slot 66 and ramp 56. This could permit each anti-rotation lug 18 to bypass the bottom of each axially extending slot 66 and ramp 56. For example, if each anti-rotation lug 18 had a lowermost edge beveled like that taught by Babson (see, e.g., Babson FIG. 3), each lug would avoid an axially extending slot 66 and ramp 56, and contact a lower portion of the wall of the bores 52, 62 instead. This would cause the vial 10 to become wedged in the bores 52, 62, thereby frustrating the operation of the automated test apparatus, because removal of the vial 10 would be difficult or impossible without operator intervention.

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Additionally, an anti-rotation lug 18 with a lowermost edge that is not substantially perpendicular to the outer surface of the body 12 would defeat the purpose of the circumferentially disposed portion 74. The circumferentially disposed portion 74 is used to lock each anti-rotation lug 18 to prevent axial translation of the vial 10. Specification, p. 14, ll. 2-4. Accordingly, if the vial 10 attempted to emerge (i.e., outwardly translate) from the vial sleeve 64, the upper edge of each circumferentially disposed portion 74 would engage each anti-rotation lug 18, thereby stopping this translation. If each anti-rotation lug 18 did not have a lowermost edge that is substantially perpendicular to the outer surface of the body 12 (e.g., like the beveled lowermost edge of Babson), each lug would present, during outward translation of the vial 10, a diminishing surface area for contact with the upper edge of each circumferentially disposed portion 74. This would prevent each circumferentially disposed portion 74 from capturing each anti-rotation lug 18, and thereby allow the vial 10 to continue outwardly translating, and potentially leave the vial sleeve, defeating another benefit of Applicants' invention.

In summary, requiring that each anti-rotation lug 18 have a lowermost edge that is substantially perpendicular to the outer surface of the body 12 ensures that the vial 10 will not:

- (i) penetrate too deeply into the bores 52, 62, thereby causing the vial 10 to jam in the apparatus and frustrate the operation of the automated test apparatus, and
- (ii) axially translate to an improper position when in the vial sleeve 64.

The structural limitation Applicants have added to claim 1 concerning the substantially perpendicular geometry of the lowermost edge of each anti-rotation lug 18 relates to an important aspect of Applicants' invention for ensuring the proper (i.e., automated) operation of Applicants' apparatus.

Applicants respectfully submit that claim 1, as amended herein, is allowable and clearly and patentably distinguished over the cited references, either alone or in combination. Because claims 2-8, 10, 12-23, 25, and 26 all depend, directly or indirectly, from claim 1, Applicants submit that these claims are allowable as well.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-8, 10, 12-23, 25, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Moore in view of Babson.

5. Claim 24 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore (U.S. Pat. No. 5,855,289) in view of Babson (U.S. Pat. No. 4,639,242), in further view of Neeley et al. (U.S. Pat. No. 5,164,575). Applicants respectfully traverse this rejection as applied to the claims as amended.

Neeley teaches the use of a portable apparatus for blood or other sample collection that places indicia, including a bar code, on a test-tube. Applicants' claim 24 depends from claim 23, which in turn depends from claim 1. Applicants respectfully submit that Neeley fails to cure the deficiencies of Moore and Babson with respect to the sole independent claim (claim 1) as discussed above. Because claim 1, as amended herein, is allowable and clearly and patentably distinguished over the cited references, either alone or in combination, Applicants respectfully submit that claim 24, ultimately depending from claim 1, is allowable as well.

Applicants respectfully request reconsideration and withdrawal of the rejection of claim 24 under 35 U.S.C. § 103(a) as being unpatentable over Moore in view of Babson, in further view of Neeley.

CONCLUSION

In view of the foregoing, Applicants submit that claims 1-8, 10, and 12-26, are clearly and patentably distinguished over the cited references, either alone or in combination, and are therefore allowable. Applicants respectfully request entry of this Amendment and Response, reconsideration, and early favorable action by the Examiner.

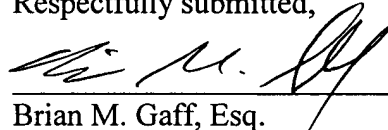
The Examiner is cordially invited to contact Applicants' undersigned representative at the number listed below to discuss any outstanding issues.

Date: October 19, 2001  
Reg. No. 44,691

Tel. No.: (617) 310-8085  
Fax No.: (617) 790-0332  
Email: [gaff@tht.com](mailto:gaff@tht.com)

VER 9/00  
GAFFBM217429.2168835\_1

Respectfully submitted,



Brian M. Gaff, Esq.  
Attorney for Applicants  
Testa, Hurwitz, & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110



**VERSION OF AMENDED ITEMS WITH MARKINGS TO SHOW CHANGES MADE**

October 19, 2001

**IN THE CLAIMS:**

1. (Five times amended) A sample vial for use in an automated test apparatus, the sample vial comprising:

a body comprising an outer surface, an open end, a closed end, and at least one anti-rotation lug about said body outer surface, the anti-rotation lug comprising a planar, longitudinally disposed surface extending radially outwardly from said body outer surface, the longitudinally disposed surface comprising a lowermost edge that is substantially perpendicular to said body outer surface;

a cap releasably engagable with said body, said cap comprising an outer surface and a torque pattern on said cap outer surface, said torque pattern comprising a plurality of radially disposed ribs; and

a seal disposed between said body and said cap so as to be capable of forming a substantially fluid-tight seal therebetween,

wherein both of the planar surface and the lowermost edge of the at least one anti-rotation lug is accessible when the cap is engaged with the body for reacting against proximate structure of the automated test apparatus when installed therein to facilitate at least one of automated removal and installation of the cap.